REMARKS

This is in response to the Office Action dated July 11, 2008.

Claims 1-47 and 49-61 are pending and at issue in this application. Claims 1, 47 and 58 are amended. Support for these amendments can be found throughout the specification, for example at paragraph 19 of the application as filed. Claims 59-61 have been added. Support for these new claims can be found throughout the specification, for example at paragraph 68 of the application as filed. Applicants submit this amendment to place the claims in condition for allowance or better condition for Appeal pursuant to 37 C.F.R. § 1.116. Accordingly entry of this amendment is respectfully requested.

Applicants note that the current outstanding Office Action appears to list claims as numbered in the September 13, 2007 Office Action, i.e., prior to the March 18, 2008 Response to the Notice of Noncompliant Amendment which renumbered claims 55-59 to 54-58 to correct a typographical error. Where the rejections in the Office Action are described, Applicants have indicated which claims have been renumbered. Thereafter in the Remarks, Applicants refer to the claims as renumbered.

Applicants thank the Examiner for the courtesies extended Applicant during the telephonic interview of September 22, 2008, the Examiner's summary of which, as contained in the Interview Summary Form (PTOL-413), has been received.

Claim Rejections - 35 U.S.C. §102

In the Office Action at page 2, claims 1, 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 58 (57 as renumbered) are rejected under U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,197,051 (Zhong). Applicants respectfully traverse.

However, solely to expedite prosecution, Applicants have amended claim 1 to recite "a single outermost drug reservoir layer having a polymer composition comprising a polymeric alloy of two or more polymers."

Zhong does not anticipate claim 1 because Zhong does not disclose or suggest (1) a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers, but rather only discloses an outermost layer comprising a single polymer, a polycarbonate-polyurethane co-

polymer (see, e.g., claim 1: "a dispersion of a polycarbonate-polyurethane polymer" (emphasis added); see also claims 3, 18 and 20). Furthermore, Zhong does not disclose or suggest (2) a coating that releases efficacious amounts of the active agent at the site of stent expansion. Instead, Zhong teaches that where the outermost layer comprises a bio-active agent, the bio-active agent is permanently attached via covalent bonding to the outermost layer (Col. 3, lines 28-32; Col. 7, lines 7-12).

Claims 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 57 all depend from claim 1, and are therefore allowable as being dependent on an allowable claim. Accordingly, Applicants respectfully request that the rejection of claims 1, 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 57 be withdrawn.

Claim Rejections - 35 U.S.C. §103

In the Office Action at page 3, claims 2, 5, 14, 23, 30, 47 and 59 (58 as renumbered) are rejected under U.S.C. § 103(a) as being unpatentable over Zhong in view of U.S. Patent No. 5,380,299 (Fearnot). Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 2, 5, 14, 23 and 30 depend from claim 1, and therefore include all of its elements. Independent claim 47 is a means-plus-function claim that requires a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers, e.g., a stabilizing polymer and a toughening polymer, and further recites a means for containing and controllably releasing the agent from the stent over an extended period. Independent claim 58 also requires a single outermost drug reservoir layer comprising two or more polymers, e.g., at least one hydrophobic polymer and at least one hydrophilic polymer, and further recites that the stent coating releases efficacious amounts of the active agent at the site of stent expansion. As discussed above for claim 1, Zhong does not teach, disclose, or suggest a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers. Nor does Zhong teach a coating that releases efficacious amounts of the active agent at the site of stent expansion, as recited in claims 1 and 58, or a means for containing

and controllably releasing the agent from the stent over an extended period, as recited in claim 47. Therefore, Zhong does not render obvious any of these claims.

Zhong discloses devices having bio-compatible substrate coatings. The bio-compatible coating of Zhong is formed from a composition comprising an aqueous emulsion or dispersion of a polycarbonate-polyurethane copolymer having one or more emulsifying agents which include at least one organic acid functional group (see, e.g., field of invention, summary of invention, detailed description and claims). The bio-compatible coating also optionally includes polyfunctional cross-linking agents that are reactive with organic acid functional group (column 5, lines 28-40). This coating can also serve as a primer for a second coating layer which contains certain bio-active agents (e.g., field of invention, column 3, lines 20-21, column 4, lines 39-41).

Nowhere does Zhong disclose or suggest a second layer comprising two or more polymers, nor does Zhong disclose or suggest a second layer comprising a polymeric alloy of two or more polymers. Instead, Zhong discloses a bio-compatible coating comprising a single polymer, i.e., a polycarbonate-polyurethane copolymer (see, e.g., claim 1: "a dispersion of a polycarbonate-polyurethane polymer" (emphasis added)), contrary to the assertions in the Office Action. Furthermore, Zhong does not teach a coating that releases efficacious amounts of the active agent at the site of stent expansion, as recited in claims 1 and 58, or a means for containing and controllably releasing the agent from the stent over an extended period, as recited in claim 47. Therefore, the compositions disclosed in Zhong are structurally different from the present claims.

As set forth in the claims and the description of the present application, e.g., paragraph 16, the inventive coatings use a system with two or more polymers (e.g., a hydrophilic and a hydrophobic polymer), which allows outstanding adhesion to substrates and the flexibility to meet the demanding requirements of vascular stents. The use of two or more separate polymers (to form, e.g., hybrid coatings) creates a drug delivery layer which permits the production, loading and elution control of a broad range of drugs or combinations of drugs from the surface of a stent. The hybrid coatings permit the release of efficacious amounts of the active agent, which may be alloyed with and deposited throughout the polymer composition, as recited in new dependent claims 59-61. The inventive hybrid polymer binder controls the drug elution rate by using, e.g., various ratios of

hydrophilic polymer to hydrophobic polymer, the combination stabilizing the drug during manufacturing, sterilization, and deployment of the stent.

Zhong does not disclose or suggest a single outermost drug reservoir/release layer comprising a polymeric alloy of two or more polymers. Nor does it disclose or suggest the system of the present invention for controlled release of efficacious amounts of an active agent. Instead, Zhong teaches that where the second coating comprises a bio-active agent, the bio-active agent must contain at least one organic acid functional group in order to permit covalent bonding with a cross-linking agent in the primer or second coating (Col. 3, lines 28-32; Col. 7, lines 7-12). In this arrangement, the bio-active agent is "permanently attached to the substrate" (Col. 3, lines 30-31), meaning that elution of the bio-active agent is not possible in the Zhong coating. Therefore, it is certainly not possible to control the elution rate of the bioactive agent by manipulating the relative ratios of, e.g., hydrophilic and hydrophobic polymers. Thus, Zhong's covalent bonding of drugs to the primer or second coating is both structurally and functionally quite different from the present invention, wherein the active agent is contained in and is later released from a single outermost drug reservoir layer comprising two or more polymers at an insertion site.

Claim 58 provides additional distinctions over Zhong. Claim 58 recites a stent having a coating comprising a primer layer having a hybrid polymer composition of at least one hydrophobic polymer and at least one hydrophilic polymer; and a single outermost drug reservoir layer having a hybrid polymer composition comprising a polymeric alloy of at least one hydrophobic polymer and at least one hydrophilic polymer, the drug reservoir layer including a drug stabilizing polymer, a toughening polymer and one or more active agents, the drug reservoir layer protecting and stabilizing the one or more active agents during sterilization and storage, the coating having sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, and releasing efficacious amounts of the active agent at the site of stent expansion.

The stent recited in claim 58 is not taught or suggested by Zhong. For example, the primer layer in Zhong is a single polymer, polycarbonate-polyurethane (see, e.g., claim 1), not the hybrid polymer composition of at least one hydrophobic polymer and at least one hydrophilic polymer recited in claim 58. Furthermore, because the outermost layer in Zhong contains only one polymer, it does not comprise at least one drug stabilizing polymer and at least one toughening polymer. And

because Zhong has these structural differences, it cannot provide the control over the rate of elution of active agent, as provided by the claimed stent. For at least these reasons, claim 58 is also patentable over Zhong.

Fearnot does not cure the defects in Zhong. Fearnot relates to an intravascular medical device having a structure shaped and sized for introduction into the vascular system of a patient including a base material and a coating of a thrombolytic agent on the base material. Fearnot does not cure the defects of Zhong because nowhere in Fearnot is a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers taught, disclosed or suggested. Nor does Fearnot teach a coating that releases efficacious amounts of the active agent at the site of stent expansion, as recited in claims 1 and 58, or a means for containing and controllably releasing the agent from the stent over an extended period, as recited in claim 47. Therefore, neither Zhong nor Fearnot, whether applied alone or in combination, render the claims obvious.

Applicants respectfully request that the rejection of claims 2, 5, 14, 23, 30, 47 and 58 be withdrawn.

In the Office Action at page 5, claims 16, 21, 22, 27, 38 and 53-58 (53-57 as renumbered, reflecting the renumbering of 55-58 to 54-57 to rectify the previous omission of 54) are rejected under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,197,051 (Zhong) because allegedly the additional elements recited in these claims would be considered obvious by one skilled in the art. Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 16, 21, 22, 27, 38 and 53-57 depend from claim 1, and therefore include all of its elements. As discussed above for claim 1, Zhong does not teach, disclose or suggest a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers. Nor does Zhong teach a coating that releases efficacious amounts of the active agent at the site of stent expansion. Finally, Zhong does not permit control of the elution rate of the active agent, as provided by the claimed invention. Therefore, Zhong does not render obvious any of these claims.

Applicants respectfully request that the rejection of claims 16, 21, 22, 27, 38 and 53-57 be withdrawn.

In the Office Action at page 6, claims 3, 6-13, 18, 19, 28, 31-34 and 39-46 are rejected under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,197,051 (Zhong) in view of U.S. Patent No. 6,663,662 (Pacetti). Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 3, 6-13, 18, 19, 28, 31-34 and 39-46, depend from claim 1 and therefore include all of its elements. As discussed above for claim 1, Zhong does not teach, disclose or suggest a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers. Nor does Zhong teach a coating that releases efficacious amounts of the active agent at the site of stent expansion. Finally, Zhong does not permit control of the elution rate of the active agent, as provided by the claimed invention. Therefore, Zhong does not render obvious any of these claims.

Moreover, Pacetti does not cure the defects of Zhong, because nowhere in Pacetti is a single outermost drug reservoir layer comprising a polymeric alloy of two or more polymers taught, disclosed or suggested. As elaborated in previous responses to office actions in this case, which are hereby incorporated by reference, Pacetti teaches a device having a non-drug containing barrier in the outermost layer. Therefore, neither Zhong nor Pacetti, whether applied alone or in combination, render the claims obvious.

Applicants respectfully request that the rejection of claims 3, 6-13, 18, 19, 28, 31-34 and 39-46 be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-47 and 49-61 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number included below.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Respectfully submitted,

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